GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:1412
ANSWERED ON:10.12.2003
EXEMPTING PENCILLIN-G FROM IMPORT REGISTRATION REQUIREMENTS
S. SAIDUZZAMAN

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether the Pharma Industry Association IDMA has made representation to DCGI regarding exemption of Penicillin-G and its salts from import registration requirements as it is used as an intermediate; and

(b) if so, the decision taken by the DCGI in this regard?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) Yes, Sir.

(b) The representations received by various manufacturers regarding giving exemption to Penicillin G and its salts from registration requirements was considered by DCG (I). Penicillin G is a drug falling within the definition of a drug under Section 3 (b) of the Drugs and Cosmetics Act and hence, rules made under Drug and Cosmetics Rules will apply according to which the drug is required to be registered for the purpose of import. The representation seeks to imply that since it is used as an intermediate for the manufacture of other drugs and not as a drug, registration should not be insisted upon. However, as per provisions of Drugs and Cosmetics Act, a drug, which can also be used as such, even if used as a raw material for the manufacturer of other drugs will require registration. The Indian Penicillin Manufacturers Association have made a plea that Penicillin G and its salts should be covered under the Registration procedure for the reasons that :-

1. Penicillin G is covered under Drug Price Control Order.

2. All the Penicillin G manufacturers are having manufacturing licence for Penicillin endorsed by the Drug Controller.

3. Penicillin G is also used for direct manufacture of Pen-G tablets.

Taking above into the consideration it has been opined that Penicillin-G is a drug and requires registration though it may be used as intermediate for the manufacture of other drugs.